Exhibit 21

Establishment Inspection Report

Zhejiang Huahai Pharmaceutical Co., Ltd., Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai 5th Avenue, Linhai, Taizhou, Zhejiang 317016 China

FEI: **3003885745**

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EI End: 08/03/2018

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1bi) Change Request PCRC-11025 [**Exhibit 101**] did not identify specific parameters the firm would use to evaluate the effectiveness of the requested change and the impact of the requested change on intermediate(s) and/or the final Valsartan API prior to implementing changes to the firm's validated manufacturing process for Valsartan API. Change Request PCRC-11025 did not specify acceptance criteria for specific parameters the firm would use to evaluate the effectiveness of the requested change and the impact of the requested change on intermediate(s) and/or the final Valsartan API prior to implementing changes to the firm's validated manufacturing process for Valsartan API. I asked Mr. Dong if the firm identified specific parameters with acceptance criteria the firm would use to evaluate the effectiveness of the requested change and the impact of the requested change on intermediate(s) and/or the final Valsartan API prior to implementing changes to the firm's validated manufacturing process for Valsartan API. Mr. Dong pointed to a table describing manufacturing operating ranges in Valsartan Process II Zinc Chloride Process Change Summary [**Exhibit 101 pages 14-16 Table 3.2**]. The table does not include acceptance criteria. I asked Mr. Dong if the firm established specific parameters with acceptance criteria which the firm used to evaluate if the isomer conversion was reduced and the yield increased. Mr. Dong again pointed to the same table.

Mr. Dong did not identify a specific parameter or parameters with acceptance criteria which indicate the effectiveness of the requested change in reducing isomer conversion and increasing yield. Mr. Jun Du, Executive Vice President, apologized and stated the change control should have stated the purpose of the change was to save money. Mr. Du further stated the cost reduction was so significant it is what made it possible for the firm to dominate the world market share.

Valsartan Process II Zinc Chloride Process Change Summary includes a comparison of the level of isomer D-Valsartan and total impurities for the three lab scale batches from the outside laboratory and three commercial scale batches manufactured by the firm [**Exhibit 101 pages 26 Table 6-1**]. The D-Valsartan (specification $\leq$ 1.0%) lab scale results ranged from 0.31% to 0.56% and the commercial scale results ranged from 0.47% to 0.56%. The commercial scale results are within the range of the lab scale results. The report does not include a comparison between the isomer results of the commercial scale validation batches with commercial batches manufactured prior to the change. The report does not compare the batch yield of the commercial scale validation batches with commercial batches manufactured prior to the change. The acceptable criteria listed in the validation protocol for Valsartan Process II Zinc Chloride Process is a list of process parameters with the critical process parameters highlighted [**Exhibit 103**]. The Validation Protocol for Valsartan Process II Zinc Chloride Process does not include acceptance criteria defining how much isomer D-Valsartan should be decreased or how much batch weight should be increased [**Exhibit 104**]. I asked Mr. Dong if the Validation Protocol for Valsartan Process II Zinc Chloride Process included acceptance criteria defining how much isomer D-Valsartan should be decreased or how much batch weight should be increased in relation to the firm's validated manufacturing process for Valsartan API. Mr. Dong stated no.